SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant SmartSignals | GxP Inventory

INTRODUCING SIGNANT SMARTSIGNALS GxP INVENTORY

A centralized, easy-to-use clinical inventory management system that can serve as the single source of truth for all inventory created and consumed during a clinical trial - from raw material to finished kit.

WHO IS GxP INVENTORY FOR?

GxP Inventory is an efficient oversight mechanism for all sponsors and CROs to track and manage all clinical trial material creation, release, and distribution activities. A versatile solution that enables centralized data within a single source of truth, it can accommodate any size supply chain, large or small.

WHAT PROBLEM DOES GxP INVENTORY ADDRESS?

GxP Inventory makes clinical trials safer for patients through better visibility and control of supplies. From sourcing drug substance ingredients to randomized patient kits, all supply chain data is in one place, not distributed across spreadsheets, emails, and external inventory management systems.

Meet Crystal, a Clinical Supplies Manager at BestPharm

CHALLENGES

- Reliance on email & spreadsheets, though they impede data security, quality control, & visibility
- Increasingly fragmented manufacturing & supply chain
- Organizational pressure to control costs & reduce waste (as much as >70% excess production)

Crystal is under huge pressure as her employer, BestPharm, races to prove the efficacy of a new Oncology drug candidate, CP-4582.

Her global supply chain starts in **Wuxi, China**, where a factory creates the registered starting materials for an API manufacturing facility in **Switzerland**. The drug substance is then shipped to a specialist drug product manufacturing company in the **Northeastern US** before being sent to a packaging company in the **Midwest US** that creates the finished, labeled patient kits to send to sites.

BestPharm is betting the future of their company on this new drug and every supply chain decision has high stakes.

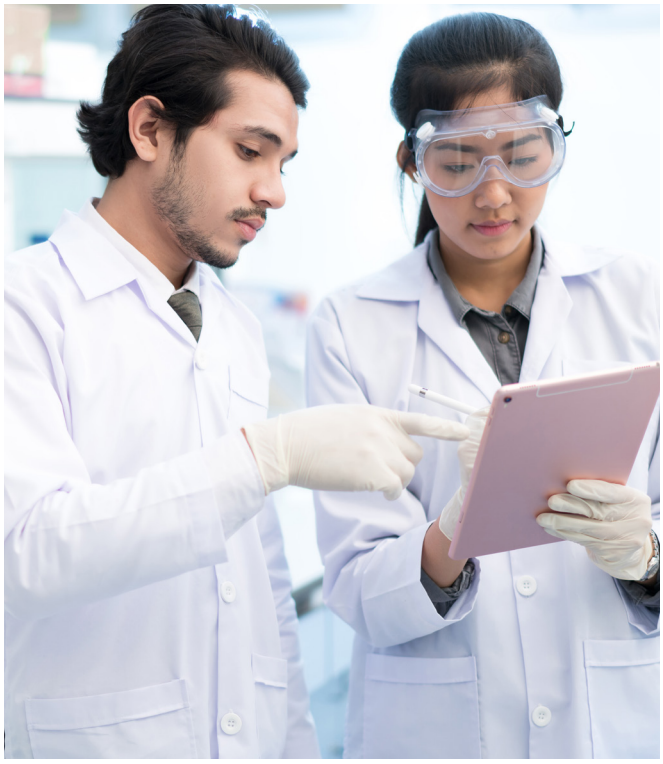
To be ready for a drastic increase in demand, she's simultaneously running technical transfer and validation to a commercial facility that will be able to support increased clinical needs in case of a best-case scenario for the Phase III read-out adding another set of external vendor data to manage with an inadequate toolset.

GxP Inventory is Designed for Real Challenges

What happens when the transfer team identifies a genotoxic impurity that's contaminated the drug substance batches over the past two years?

As required by law, Crystal notifies the FDA, who ask for a full traceability report and product recall within 24 hours to ensure no more particiants are at risk of receiving the contamined drug substance.

Crystal immediately places all 5 RTSM systems on hold for each of the 5 studies, freezing dispensation and blocking administration of site visits. Because RTSM systems don't reflect batch genealogy, Crystal must now systematically re-trace all input batches to determine where her supply chain has been contaminated.



Enter GxP Inventory:
Mitigating the Disaster

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Without GxP Inventory

- Contact all four drug supply chain partners across four different time zones to request batch tracking info
- Wait for partners to triage and process request, including collating and scanning paper batch records where needed
- Consolidate and cross-reference each partner's supply chain information to determine which patient kits might have been contaminated
- Prepare full lot genealogy report for CP-4582 Program

APPROXIMATE TIME TO COMPLETE:
24–72 hours

Failure to comply could result in BestPharm's license to operate being revoked, and lack of visibility to contaminated kits increases the risk to patient safety.

With GxP Inventory

- Crystal logs into her single system of record for Supplies to generate the lot recall with full genealogy report at the touch of a button
- The lot recall report instantly returns patient kit IDs and batch numbers for affected drug substance so Crystal can direct partners and sites to quarantine the material and remove contaminated batches from the supply chain

APPROXIMATE TIME TO COMPLETE:
<5 minutes

This doesn't just fulfill an FDA requirement, it proves and assures BestPharms commitment to patient safety.

GxP Inventory offers an accessible oversight mechanism to make clinical trials safer for patients and simpler for supplies professionals to do what they do best.

WHO IS SIGNANT HEALTH?

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Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.